## REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**Claim Status and Amendments**

Claims 1, 4-8 and 10-16 are pending.

Claims 9, and 17-23 stand canceled without prejudice or disclaimer.

Claims 2 and 3 are now canceled without prejudice or disclaimer.

Claims 1, 4-7, 10-11, and 13-15 currently are amended. No new matter is added by the amendments. Support for the amendments can be found throughout the application as filed. Claims 1, 4-7, 10-11, and 13-15 are amended to remove the recitation of the term "about," consistent with the suggestion by the Office. Claim 1 is amended to recite the ratio to be "0.07 or greater." Support for this amendment can be found, for example, in claim 3 now canceled. Claim 1 is also amended to recite "consisting essentially of" to further define the invention.

The cancellation and amendment to the claims is not intended to be a dedication of the canceled subject matter to the public. Applicant reserves the right to file one or more continuations, divisionals or continuation-in-part applications directed to the canceled subject matter.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1, 4-8, and 10-16 are pending and are under consideration.

**Notes**

Applicant thanks the Office for correcting the inventorship by adding inventors, Brian M. Strauss and Brian Canfield.

Applicant also thanks the Office to acknowledge Declaration of Brian M. Strauss submitted under 37 C.F.R. §1.132 filed on February 14, 2008.

**Claim rejection under 35 U.S.C. §112, second paragraph**

Claims 1-13 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to correctly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, the Office alleges that the recitation of "from greater than about" in the claims is indefinite. *See* page 3 of the Office Action.

To be clear, Applicants intended to refer to an amount of contrast agent that is greater than 40% but not 40%. Without acquiescing to the proprietary of the rejection and solely to expedite prosecution, Applicants have amended instant claims to remove the term "about." Withdrawal of this rejection is respectfully requested.

**Claim rejection under 35 U.S.C. §102(e)**

1. Claims 1-2, 4-8, and 10-16 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Whalen et al. (US 2002/0090339).

The Office alleges that Whalen et al. teach a biocompatible polymer at a concentration of from about 2 to about 50 weight percent; a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent; and a biocompatible solvent from about 10 to about 88 weight percent. The Office further alleges that the cited reference teaches all the critical elements required by the claims. *See* pages 4-5 of the Office Action.

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Applicants submit that Whalen et al. do not teach all the critical elements of the instant claims. Whalen et al. teach biocompatible contrast agent to be from about 10 to about 40 weight percent. See for example, Whalen et al. page 2, paragraph [0040]. Therefore, Whalen et al. do not teach greater than 40 to 60 weight percent of water-insoluble, biocompatible contrast agent, as in the claimed invention.

Furthermore, Whalen et al. do not teach a ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent to be 0.07 or greater.

In the absence of the teaching of all the claim elements in Whalen et al., withdrawal of this rejection under 35 U.S.C. §102(e) is respectfully requested.

2. Claims 1-2, 4-8, and 10-16 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Patterson et al. (US 2004/00224864).

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

The claims as currently amended are directed in part to a composition consisting essentially of a biocompatible polymer, a biocompatible solvent and a biocompatible contrast agent. Therefore, the amended claims are limited in scope to the specified materials and those that do not materially affect the basic and novel characteristic(s) of the claimed invention.

Patterson et al. teach sterilization of embolic compositions comprising hydroxyl-containing rheological modifier(s) using irradiation techniques. The hydroxyl-containing rheological modifier imparts shear thinning and pseudo-plastic properties to the composition which materially changes the viscosity characteristics of the pre-sterilized composition at a given shear stress compared to the viscosity at static conditions. *See* Patterson et al. page 3, paragraph [0042].

Therefore, Patterson et al. do not anticipate instant claims since the hydroxyl-containing rheological modifier(s) is not within the scope of the instant claims.

In light of the above, withdrawal of this rejection under 35 U.S.C. §102(e) is respectfully requested.

**Claim rejection under 35 U.S.C. §103(a)**

Claims 1-3 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Whalen et al. (US 2002/0090339); Patterson et al. (US 2004/0224864)[1] in view of Evans et al. (US 5,695,480).

The Office admits that Whalen et al. or Patterson et al. fails to disclose explicitly the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent to be about 0.07 or greater. The Office alleges that Evans provides a motivation and expectation of success by using the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent of about 0.0625 in embolic composition comprising similar component used in overlapping range of concentrations as those claimed in the instant application. *See* pages 6-7 of the Office Action.

Applicants submit that the Office has not met their burden of showing the requisite motivation to use the teaching of Whalen et al., Patterson et al. in view of Evans et al. to arrive at the currently claimed invention. Assuming *arguendo* that the Office has met its burden, Applicant has demonstrated surprising and unexpected effects of using a high amount of contrast agent to improve visualization while still maintaining a cohesive precipitate.

> To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable

[1] Patterson et al. is co-owned with this application and Applicants would like to bring to the Office's attention that a Request for Express Abandonment of the Patterson eta l. application is being filed on even date herewith.

expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicant traverses the rejection for the following reasons.

Applicant's amended claims are directed to a composition consisting essentially of:

from 2 to 40 weight percent of a biocompatible polymer;

a biocompatible solvent; and

from **greater than 40 to 60 weight percent** of a water-insoluble, biocompatible contrast agent;

wherein the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent is **0.07 or greater**; and

further wherein the weight percent of each component is based on the total weight of the composition.

The two features of the claimed invention are, namely, over 40 to up to 60 weight percent of water-insoluble, biocompatible contrast agent and the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent to be 0.07 or greater.

Unexpectedly, the higher concentration of the water-insoluble, biocompatible contrast agent retains the efficacy of the composition for endovascular surgical procedures by providing adequate flowability through the microcatheter and forming a coherent precipitate *in vivo* without the undesired fragmentation and the shedding of the particles. *See* page 5, paragraph [0021] of the application as filed. Applicants note that the Declaration by Brian M. Strauss filed February 14, 2008, demonstrates that greater than about 40 to about 60% contrast agent and a ratio of biocompatible polymer to water-insoluble biocompatible contrast agent of greater than 0.055 (greater than 0.07 in instant amended claims) results in a polymer precipitate that is relatively cohesive and provides a high level of visualization during delivery. This is an improved composition over what was known in the art.

Example 2 and Figure 1 of the instant application clearly shows the difference in visibility under fluoroscopy between conventional embolic compositions comprising no more than 40% contrast agent (sample #1) and the compositions comprising higher concentration of

biocompatible contrast agent where the ratio between the biocompatible polymer and the biocompatible contrast agent is 0.077 (sample #10). Figure 1 shows that the composition having the concentration of the biocompatible contrast agent greater than 40% and the ratio between the biocompatible polymer and the biocompatible contrast agent greater than 0.07 is significantly better in radioopacity than the compositions with less than 40% contrast agent.

Therefore, it is critical for the composition to have both 40 to 60 weight percent of water-insoluble, biocompatible contrast agent and the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent to be 0.07 or greater, in order to provide a composition with improved visualization, adequate flowability and cohesive precipitation.

The table below illustrates the comparison of the features of the claimed invention with the cited art.

| | **Biocompatible polymer** | **Biocompatible contrast agent** | **Biocompatible solvent** | **Ratio between biocompatible polymer and biocompatible contrast agent** |
|---|---|---|---|---|
| **Claimed invention** | 2 to 40 weight percent | greater than 40 to 60 weight percent | 20 to 58 weight percent (claim 13) | greater than 0.07 |
| **Whalen et al.** | 12 to 50 weight percent | 10 to 40 weight percent | 10 to 78 weight percent | |
| **Patterson et al.** | 1 to 12% | 20 to 55% | No specific amount disclosed | |
| **Evans et al.** | 2.5 to 8 weight percent | 10 to 40 weight percent | 52 to 87.5 weight percent | |

Neither of Whalen et al., Patterson et al. or Evans et al. teach or suggest a ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent to be 0.07 or greater. Additionally, neither of Whalen et al. or Evans et al. teach or suggest greater than 40 to 60 weight percent of the biocompatible contrast agent.

Therefore, neither of the cited references teach or suggest all of the claim limitations.

Whalen et al. do not suggest or motivate a person of ordinary skill in the art to use greater than 40 to 60 weight percent of the biocompatible contrast agent because Whalen et al. uses 10 to 40 weight percent. A person of ordinary skill in the art will have no reasonable expectation of success if using more than 40% contrast agent since an increase in the concentration of the biocompatible contrast agent can affect any number of variables in the properties of the composition ranging from flowability, coherent precipitation, fragmentation, and visibility. *See* pages 4-5, Example 2, and Figure 1 of the application as filed.

Meanwhile, Patterson et al. also do not suggest or motivate a person of ordinary skill in the art to arrive at the claimed composition. The compositions of Patterson et al. are entirely different from the composition of instant claims. The composition of Patterson et al. is directed to a sterilized embolic composition comprising a hydroxyl-containing rheological modifier in an effective amount to impart shear thinning, pseudo elastic properties to the composition. The hydroxyl-containing rheological modifier materially changes the viscosity characteristics of the pre-sterilized composition at a given shear stress. See Patterson et al., page 3, paragraph [0042].

Therefore, a person of ordinary skill in the art will not be motivated to exclude this critical feature of Patterson et al. and use a high concentration of contrast agent with the biocompatible polymer to arrive at the composition of the claimed invention. The person of ordinary skill in the art will have no reasonable expectation of success since the viscosity of the composition of Patterson et al. and the claimed invention will be different from each other and it cannot be envisaged if the resulting composition after excluding the rheological modifier can form a cohesive precipitate.

The Office's assertion that Evans et al. provides a motivation and expectation of success by using the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent of about 0.0625 in embolic composition comprising similar component used in overlapping range of concentrations, is in error.

Firstly, Evans et al. do not teach greater than 40 to 60 weight percent of the biocompatible contrast agent as in the claimed invention. Therefore Evans et al. do not have overlapping range

of concentrations. Secondly, Evans et al. do not specifically teach a ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent of about 0.0625. There is no teaching of a specific ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent, in Evans et al. The Office has apparently calculated this ratio from the concentrations of biocompatible polymer and biocompatible contrast agent. However, Evans et al. provides no suggestion or motivation to a person of ordinary skill in the art to pick a certain ratio from all the possible ratios that can be calculated from the concentration of the biocompatible polymer and the biocompatible contrast agent and arrive at the greater than 0.07 ratio of the claimed invention.

There is no reasonable expectation of success to a person of ordinary skill in the art to pick a ratio of greater than 0.07 of the biocompatible polymer to the water-insoluble biocompatible contrast agent and expect it to result in a composition that provides adequate flowability, coherent precipitation, minimal fragmentation, and higher visibility.

Therefore, the cited references do not teach, suggest or motivate a person of ordinary skill in the art with any reasonable expectation of success to use greater than 40 to 60 weight percent of the biocompatible contrast agent where a ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent to be 0.07 or greater to arrive at the claimed invention.

In light of the above, withdrawal of this rejection under 35 U.S.C. §103(a) is respectfully requested.

**Conclusion**

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or

incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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